incentive because they are skeptical of the drug's efficacy, safety and cost. Thus, for example, several physicians who Relator Strunck courted for the speaker program - including Ute Traugott (Rye, NY), Renee Elkin (Bronx, NY) and David Duncan (Mt. Kisco, NY) - refused the inducement.

4. Questcor Illegally Uses Sham "Consulting Fees" to compensate Doctors Who Prescribe and Promote H.P. Acthar Gel.

196. Another way in which Questcor has illegally incentivized and rewarded physicians to prescribe and promote H.P. Acthar Gel is through the payment of sham consulting fees. For example, Questcor has paid Dr. Pere $2,000 per program to talk to Questcor's own sales specialists about how to sell H.P. Acthar Gel to physicians.

5. Questcor Induces Physicians to Prescribe H.P. Acthar Gel by Offering Free Business Services, Which Also Have the Effect of Generating Fraudulent Reimbursements.

a. The Acthar Support and Access Program (ASAP)

197. Questcor knows that virtually all prescriptions for H.P. Acthar Gel will require prior authorization if they are to be reimbursed by Government Programs or private insurance. Questcor also knows that because of the drug's high cost, limited approval and ominous safety profile, Government Programs and private insurers typically set rigid requirements for when they will approve reimbursement for H.P. Acthar Gel.

198. Questcor also knows that the process for obtaining prior authorization for H.P. Acthar Gel - even for a patient who legitimately requires the drug for use within its FDA approval - can extract a significant time and financial burden on a. busy medical practice.

199. Thus, Questcor established the Acthar Support and Access Program (ASAP), which operates like a reimbursement "hub" for physicians. The program is managed by Curascript (the specialty pharmacy that is the exclusive distributor for H.P. Acthar Gel), and it handles all aspects of the prior authorization process for physicians who prescribe H.P. Acthar Gel. Questcor probatively promotes the ASAP program to physicians because it knows the program will add value to a physician's business, and induce the physician to prescribe H.P. Acthar Gel in lieu of Solu-Medrol.

200. The first step in the ASAP program occurs when Questcor's sales specialist visits with a medical practice. At the direction of Questcor regional managers, the sales specialists, including Relator Strunck, probatively tell physicians that the only way that they are allowed to prescribe H.P. Acthar Gel is by enrolling the patient in the ASAP program, even though that simply is not true.

201. Sales specialists are trained to, and do, tell physicians that they personally will benefit from the ASAP program because Curascript will undertake responsibility for managing the prior authorization process from beginning to end - a substantial benefit to physicians and their staff. They also tell physicians that enrolling the patient in the ASAP program makes the patient eligible to participate

in (i) Questcor's Co-Pay Assistance Program; (ii) Questcor's Patient Assistance Program; and (iii) the National Organization of Rare Disorders (which is not affiliated with Questcor).

202. Questcor sales specialists are trained to, and do, tell physicians that the first step in the ASAP program is for the physicians to complete an ASAP enrollment form for each patient, listing among other things the patient's biographical data, insurance data, diagnosis and specific prescription (i.e. number of vials and syringes).

203. Questcor instructs its sales specialists to tell physicians that, in order to overcome prior authorization obstacles, both the ASAP enrollment form and the patient's chart must indicate that the patient previously, but unsatisfactorily, tried intravenous Solu-Medrol or oral prednisone even if that is not true. Relator Strunck did this at the direction of Regional Manager Ken Miller, and he understands that other sales specialists, including Stacy Clancy and others in her Philadelphia-area sales district, did this as well.

204. In Relator Strunck's experience, physicians and their staff who agreed to prescribe H.P. Acthar Gel did not "balk" at the instruction to falsely state on the ASAP enrollment form and in patient charts that the patient had tried Solu-Medrol or oral prednisone and had an unsatisfactory result, Instead, ironically, the most frequent "push-back" that Relator Strunck received from the physicians he called on was that their patients were responding well to treatment with Solu-Medrol, and that they did not require a different therapy.

205. Among the physicians who either directly or through their staff agreed to (i) prescribe an off label five-day course of treatment with H.P. Acthar Gel for acute exacerbations of MS, and (ii) falsely state for reimbursement purposes that the patient had tried but failed with alternate therapy, were Dr. Alice Rusk (Stamford/Greenwich, CT), Dr. Nilay Shah (Mt. Kisco, NY) and Dr. Sarla Devi (Yonkers, NY).

206. Once Curascript receives an ASAP enrollment form, it notifies Questcor of the prescription, and a Questcor Regional Reimbursement Manager (for Relator Strunck, it was Michael Hoffman) relays the information to the sales specialist assigned to the prescribing physician. The sales specialist then is required by Questcor to contact the prescribing physician to provide instruction as to how to facilitate payment, perhaps through the Co-Pay Assistance Program or the Patient Assistance Program, discussed infra, when Curascript calls to complete the transaction.

207. On the rare occasion that a prior authorization request is denied by a Government Program or private insurer, Questcor instructs its sales specialists to "coach" physicians and their staff on how to "win" the appeal by, among other things, overwhelming the insurer with so many reimbursement requests and appeals that it ultimately relents. This cynical strategy has proven to be quite successful.

208. Questcor's Associate Director for Specialty Distribution and Payer Relations, Jason Camp, authored an email to the entire sales force and senior

Questcor sales management on June 20, 2011 in which he stated that as a result of the Questcor's strategy of "*continually pressuring Federal BCBS by requiring them to review each Acthar referral at their weekly Physician Review meetings*" and *"continually tying up their resources,"* Federal BCBS had *"ultimately conceded and has agreed to provide authorization for all Acthar MS referrals that meet [specified] coverage criteria"* (i.e. active flare, detailed history with Solu-Medrol and current disease modifying therapy). Mr. Camp's email confirmed that Questcor's strategy had been to:

1) Work with HCPs to submit referrals that clearly met coverage criteria (in active flare), and have detailed history of patient;

2) Coach HCP offices to appeal, and work with them throughout the process[; and]

3) ROSS team identifying key decision-makers at Federal BCBS responsible for the authorization process and called on them continually to make them justify each denial.

209. Mr. Camp described this development as *"an important breakthrough with Federal BCBS, one of the most difficult payers in the country."* According to Mr. Camp, although Federal BCBS had approved only 2 of 40 prior authorization requests in 2010, it approved 14 of 15 requests between April 18, 2011 and June 20, 2011 alone.

210. Questcor's ASAP program is improper not simply because it provides a valuable service to physicians to induce them to prescribe H.P. Acthar Gel in lieu of less expensive, equally or more effective alternatives, but also because the program itself is deceptive in the manner in which it encourages reimbursement by Government Programs.

b. The Co-Pay Assistance Program and the Patient Assistance Program

211. Questcor's Co-Pay Assistance Program is a program by which Questcor provides insurance co-pay assistance to a patient whose household income does not exceed a certain threshold, which Relator Strunck believes to be in the range of $50,000 per year. For these patients who are suffering from MS, including patients who are Medicare beneficiaries, Questcor attempts to keep their co-pay to $50 or less.

212. Questcor's Patient Assistance Program is a program by which Questcor provides full reimbursement for uninsured patients whose household income does not exceed a certain threshold. Questcor instructs its sales specialists to actively promote the Co-Pay Assistance Program and the Patient Assistance Program to healthcare providers, using it as a means to overcome their objections to prescribing H.P. Acthar Gel in lieu of Solu-Medrol. Questcor places particular emphasis on promoting these programs for patients who are Medicare beneficiaries, telling physicians that they should ignore the high cost of the drug since the patient's out-of-pocket cost will be, at most, $50.

213. Questcor historically "self funded" the patient assistance programs. Questcor used the PAP as a sales tools and illegal inducement. The Sales Representative who specifically this the PAP as such are Mike Hoffman, Jason Camp, Art Veno, Rob Santa, Cris Hoven, Corrie Prato, Bob Bobeck, Nick Brunetti, Nevan Rushing.

214. The U.S. Department of Health and Human Services, Office of Inspector General, has recognized that programs such as Questcor's Co-Pay Assistance Program and Patient Assistance Program present significant potential for fraud and abuse, particularly if the practice is intended to induce or reward referrals of Federal health care program business. *See OIG Advisory Opinion 09-04 (May 11, 2009) (addressing a tax-exempt, charitable organization's practice of providing financial assistance with cost-sharing obligations associated with certain advanced diagnostic testing owed by financially needy patients, including Medicare beneficiaries); OIG Advisory Opinion 06-10 (September 14, 2006) (addressing a tax-exempt, charitable organization's practice of providing certain therapy management services and assistance with Medicare cost-sharing obligations to financially needy Medicare beneficiaries).*

c. Reimbursement Advisory Boards

215. Additionally, Questcor has sponsored "Reimbursement Advisory Boards" in which a Questcor representative, such as Jason Camp, hosts a dinner program for physician office staff (identified by sales representatives based on their script writing potential) during which he instructs them on how to navigate the

prior authorization process and pays them $500 - $1,000 for their time. Examples of Reimbursement Advisory Board events include:

(i) an event for five people at "Shadows on the Hudson" restaurant (Poughkeepsie, NY) on March 1, 2011 led by Questcor's Regional Reimbursement Manager Michael Hoffman and paid speaker Dr. Alan Perel;

(ii) an event for seven people in Patterson, New Jersey on July 21, 2011 led by Questcor's Product Director for MS Marketing (Sangeeta Prasad) and Questcor's Associate Product Manager for MS Marketing (Andrea Gasparino); and

(iii) an event in Northern New Jersey on August 2, 2011 led by Questcor sales specialist Christine Trafficant).

(iv) Questocor and Mallinckrodt have continued this practice but it grew in size and scope. They would fly the doctors to various locations. The marketing department began heading these meetings. Many of the doctors were flown to Las Vegas or Orlando for a weekend meeting. Mallinckrodt then started calling them "speaker training" meetings. As an example Amos Katz M.D. after he attended one of these meetings in 2016 in Orlando. The marketing department would have the physicians review potential marketing materials and have them give feedback.

C . Questcor Uses Free Vials of Acthar As An Inducement to Physicians In Order to Induce Them to Promote and Prescribe H.P. Acthar Gel.

216. Questcor maintains a "free vial" Program which was limited to use for children in hospital with infantile spasms.

217. Questcor then illegally employed this program to induce referrals for H. P. Achtar Gel. As used improperly with MS, the program should more aptly be referred to as *"Prescribe One and Get One Free"* Program.

218. In order to induce referrals, physicians are offered a free vial *(currently valued at over $38,000 dollars per vial)* for a patient, and when "approved"for the program, it is expected and required that the physician will also simultaneously put in a referral for a paid vial for that patient, essentially, creating a one for one trade off.

219. The essence of the "free vial" program *(currently valued at over $38,000 dollars per vial)* is to induce neurologists with one free vial for each patient to get them started on a five day dosing regimen or a pulse therapy program. While it is unlimited for the physician, it is limited to one vial per patient with the idea that physician orders the vial for that patient at the same time.

220. Joe Citkowski, (the sales representative and Key Opinion Leader (KOL) for Lisa Pratta's region) contacted her by phone on or about October 2, 2013. Referring to Dr. Amos Katz, Citkoswki told Lisa ". . . *I am signing these offices up*

for our free sample vial program[15]. Citkowski's goal was to present the "free vial" program to Dr. Katz, telling him that *"he could use a free vial for each patient to get them started and then to submit a referral for a 5 day course of therapy to Medicare or the patient's commercial insurance."*

221. The proposal to Dr. Katz which was made by Joe Citkowski (KOL) and John Stabile (Regional Manager) was reviewed and approved by Darlene Romine (VP Sales), Jason Camp (Director of Reimbursement), and Eldon Mayer (President). This approval was accomplished via a series of text messages that occurred between December 21st and 22nd, 2014. Attached as Exhibit N are the following:

- Email dated 1/03/2014 from John Stabile, regional Manager to Joe Citkowski (KOL) and Lisa Pratta enclosing the approvals for 5 separate "starter vials" for Dr Amos Katz in connection with the Free Vial program;

- Five (5) separate Sample Request Forms with unique ID numbers for (1) 5 ml vial of H.P. Achtar Gel at the bottom

222. John Stabile, in his email, tasks Citkowski with taking *"the lead with the service and management of the vials in Katz's office"* since he has *"experience from other centers."* Citkowski is also directed to advise Darlene Romaine (VP Sales) when each vial is distributed. It is important to emphasize that this Program, and the five (5) vial authorization, is nevertheless distributed to the Physicians, in this case Dr Katz, on a one for one referral basis, *i.e., get one free and*

[15] This Program is only for hospitals who have patients with infantile spasms

then prescribe one, . . . get one free and then prescribe another and so on. As an example of this, during a training session on January 8, 2014 at Dr. Katz's office to implement the Free Vial Program, Joe Citkowski emphasized to Dr. Katz's nurse, Michelle Emmons, that upon delivery of the free vial (currently valued at over $38,000 dollars per vial), a referral for a paid vial must be received prior to the delivery of a second free vial.

223. A physician, like Dr. Katz can order an unlimited amount of vials. Dr. Katz and other physicians get 1 or 2 forms each time to be used for new and existing patients. Once a physician is "approved" for the program, it is a blanket approval.

224. Citkowski stated that he is doing this now for Dr. Dina Jacobs MD at the University of Pennsylvania Hospital who has begun to subscribe based on the foregoing. He also advised Lisa that he was completing pre filled out referral forms for Dr. Jacobs. Citkowski stated that he *"sold Acthar to Dr. Jacob using the 5 day (one vial) dosing and he is filling our her forms for the 5 day dosing."*

225. John Stabile advised Relator Pratta that one physician has used 100 free vials, but did not name the physician. This program is meant to induce new users to try Achtar and induce existing referring physicians to use more.

D. Questcor Violated Multiple State' Bans on Gifts For Physicians

226. Doctors who have close relationships with drug makers tend to prescribe more, newer and pricier drugs regardless of the drugs' value compared to

less expensive medications. *See Gardiner Harris, Doctors' Ties to Drug Makers are Put on Close View, N.Y. TIMES, March 21, 2007, available at http:llwww.nytimes.com12007/03/21 /us/2 I drug.html? l =2&pagewanted=l &ref-·us&ores login.* To contain the costs associated with such "close relationships" among drug makers and healthcare professionals, several states enacted regulations beyond those provided by federal law and relevant state and federal anti-kickback laws discussed in greater detail infra. Three of these states - Massachusetts, Minnesota and Vermont - curtailed much of the "wining and dining" that drug makers had used to influence healthcare professionals and prohibited a variety of payments and gifts as having no purpose other than to establish a "close relationship." These three states and several others, including California, Maine, West Virginia and the District of Columbia, established reporting requirements related to marketing to healthcare professionals

227. Through its regular sales practices described herein, Questcor engaged in direct violations of the gift laws of Minnesota and likely other states by, inter alia, paying for dinners for providing business consulting services and other gifts that had no bona fide medical explanation or reason.

228. These practices are part and parcel of Questcor's sales practices nationally, and the violation of such gift laws is known to, and countenanced and supported by, Questcor regional and national sales managers.

XI. Defendant's Fraudulent Statements and Actions Were Material to the Government's Payment Decision and Violate The False Claims Act

A. Materiality Under The FCA

229. Section 3729(b)(4) of the FCA defines materiality similar to that found in other federal statutes: "[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

230. The Supreme Court, in *Escobar*,[16] addressed whether or not whether Section 3729(a)(1)(A)'s materiality requirement is governed by Section 3729(b)(4) or derived from the common law, stated that under any understanding of the concept, materiality "look[s] to the effect on the likely or actual behavior on the recipient of the alleged misrepresentation."

231. Using Tort and Contract law as examples, the *Escobar* Court stated a "matter is material" in two circumstances: (1) "[It] a reasonable man would attach importance to [it] in determining his choice of action in the transaction"; or (2) if the defendant new or had reason to know that the recipient of the representation attaches importance to the specific matter "in determining his choice of action," even though a reasonable person would not. Restatement (Second) of Torts § 538, at 80. Materiality in contract law is substantially similar. See Restatement (Second) of Contracts§ 162(2), and

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[16] *United States ex rel. Escobar* 579 U.S._, 2016 WL 3317565, slip op., No. 15-7 (June 16, 2016),

Comment C, pp. 439, 441 (1979). ("A misrepresentation is material only if it would 'likely ... induce a reasonable person to manifest his ascent,' of the defendant, knows that for some special reason (the representation) is likely *to* induce the particular recipient *to* manifest his ascent to the transaction.) [emphasis added)

B. Defendants Violations of The Anti Kickback Act ("AKS") Are Material and Constitute a False Express Certification Under the FCA

232. The Fraudulent Marketing Scheme, including the kickbacks described herein, violates the Federal Anti-Kickback Act[17] ("AKS") and was implemented with the intent to induce physicians to agree to prescribe H.P. Acthar Gel, knowing that such prescriptions would be reimbursed by Government Health Care Programs, through a pattern of corrupt and illegal conduct, in violation of the federal False Claims Act, 31 U.S.C. § 3729.

233. The agreements between physicians and Questcor were a clear quid pro quo. Questcor offered participation in these quid pro quo arrangements. Physicians who primarily used Solu-Medrol in lieu of H.P. Acthar Gel were not offered the same valuable benefits.

234. Questcor's Fraudulent Marketing Scheme served its intended purpose, as it induced (i) doctors to prescribe H.P. Acthar Gel in lieu of cheaper alternatives for both on- and off-label uses, and (ii) the submission of claims for

[17] The Medicare, Medicaid and Anti-Kickback Act ("AKA") 42 U.S.C. §1320a-7b(b)

those prescriptions for reimbursement by Government Health Care Programs, which did, in fact, provide reimbursements for those off-label uses, were for medically unnecessary uses.

235. At least in part, as a result of Questcor's illegal sales and marketing practices, H.P. Acthar Gel has been heavily used for the treatment of Government Health Care Program beneficiaries.

236. The Federal Courts have determined that compliance with the AKS is material to the Government payment decision and is a precondition of payment. This conclusion is "rendered inescapable when the purpose of the Anti–Kickback Statute is considered within the context of the Medicare statute." *42 U.S.C. § 1395y(a)(1)(A)*. Moreover, courts, without exception, agree that compliance with the Anti–Kickback Statute is a precondition of Medicare payment, such that liability under the False Claims Act can be predicated on a violation of the Anti–Kickback Statute[18].

237. The Medicare program requires providers to affirmatively certify that they have complied with the AKS. Failure to comply with the kickback

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[18] *See, e.g., Willis v United Health Group,* 2011 WL 2573380 (2011), ("Compliance with the [Anti–Kickback Statute] is clearly a condition of payment under Parts C and D of Medicare); *United States ex rel. Kosenske v. Carlisle HMA, Inc.,* 554 F.3d 88, 94 (3d Cir.2009) ("Falsely certifying compliance with the ... Anti–Kickback Act[ ] in connection with a claim submitted to a federally funded insurance program is actionable under the [False Claims Act]."); *Pogue,* 565 F.Supp.2d at 159 ("Legion other cases have held violations of [the Anti–Kickback Statute] ... can be pursued under the [False Claims Act], since they would influence the Government's decision of whether to reimburse Medicare claims."); *Rogan,* 517 F.3d at 452 (rejecting the argument that a kickback was immaterial to the validity of Medicare and Medicaid claims); *United States ex rel. Schmidt v. Zimmer, Inc.,* 386 F.3d 235, 243 (3d Cir.2004) ("A certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare program.");

laws, therefore, is, in and of itself, a false statement to the government."); *United States ex rel. Smith v. Yale Univ.*, 415 F.Supp.2d 58, 91 (D.Conn.2006). A false certification establishes the "falsity" of a claim under the FCA. This was emphasized by Congress in the 1986 Amendments to the FCA stating "each and every claim submitted under a contract, loan guarantee or other agreement which was originally obtained by means of false statements or other corrupt and fraudulent conduct, or in violation of any statute or appropriate regulation, constitutes a false claim." S.Rep. No. 99-345 at 9 (1986), reprinted in 1986 U.S.C.C.A.M. 5266, 5274. Medicare Regulations and the CMS Provider Agreement expressly provide that certification is a precondition to governmental reimbursement. In order to obtain reimbursement and as a condition to governmental payment, providers must certify that they are in compliance with the terms on the Provider Agreement; *Bidani,* 264 F.Supp.2d at 615–16 (finding a violation of the Anti–Kickback Statute "material to the government's treatment of claims for reimbursement" and that to find otherwise, "would put the government in the position of funding illegal kickbacks after the fact"); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.,* 115 F.Supp.2d 35, 43 (D.Mass.2000) (O'Toole, J.) (holding that alleged violations of the Anti–Kickback Statute were sufficient to state a claim under the False Claims Act, despite no express certification of compliance with applicable law); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.,* 20 F.Supp.2d 1017, 1047 (S.D.Tex.1998) ("[E]xplicit certifications of compliance with relevant

healthcare laws and regulations ... provided evidence that the government conditioned its approval, payment and Defendants' retention of payment funds on those certifications.").

C. Defendants Promoted and Marketed H.P. Achtar Gel For Use That Was Medically Unnecessary in Violation of 42 U.S.C. 1395(y)(A)1)(a)

238. No payments may be made under the Medicare and Medicaid programs for expenses incurred for items and services, including drugs that are not 'reasonably necessary' for the diagnosis and treatment of an illness or injury. See, 42 U.S.C. § 1395y(a)(1)(A).

239. The (i) 'misbranding," (ii) deceptive, false and misleading promotion of H.P. Achtar Gel for off -label uses, (iii) the myriad of kickbacks and illegal incentives described herein, (iv) promoting H.P. Achtar Gel in a manner that is detrimental to the patient's health and well-being and (v) failure to disclose all the promotional and marketing materials to the FDA as required resulted in H.P. Achtar Gel being used in a manner that was medically unnecessary in violation of 42 U.S.C. 1395(y)(A)1)(a). Each of these items, individually and collectively, are material to the Government payers because it is reasonable to infer that this information would be important to the Government in deciding whether to still pay for the drugs.

240. If Defendant had notified the Government Health Care Programs, FDA, States and/or the federal government of the above, they would have refused

to pay for the drug. Using the "reasonable person" standard discussed in *Escobar,* it is certainly plausible to conclude that the Government payers did "attach importance" and it does "influence" payment decisions by the Government to the above facts and circumstances

D. Defendants Failed to Disclose It's Non Compliance With Statutory and Regulatory Requirements in Promoting and Marketing H.P. Achtar Gel

241. An FCA violation occurs under implied false certification when a Defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the noncompliance with a statutory, regulatory, or a contractual requirement. Defendants actions in knowingly distributing H.P. Achtar Gel in an unsafe manner, using deceptive, misleading and false promotion and marketing means and methods, using kickbacks to induce prescriptions, making implicit representations that consisted of half truths regarding H.P. Achtar Gel to Government Agencies such as FDA and the Government Health Care programs, and express representations regarding compliance withe AKS to Federal Payers caused the filing of false claims to the Government by the Pharmacy distributors used by Defendants.

242. These actions make the claim for reimbursement "false" under the FCA because they are legally false as a result of Defendants breach of implied and express certifications which included misleading omissions, that would have been important to the Government Health Care Programs in deciding whether to pay for

the goods. A false certification establishes the "falsity" of a claim under the FCA. This was emphasized by Congress in the 1986 Amendments to the FCA stating "each and every claim submitted under a contract, loan guarantee or other agreement which was originally obtained by means of false statements or other corrupt and fraudulent conduct, or in violation of any statute or appropriate regulation, constitutes a false claim." S.Rep. No. 99-345 at 9 (1986), reprinted in 1986 U.S.C.C.A.M. 5266, 5274.

243. Medicare, Medicaid and other government funded health insurance payors, such as TRICARE and the Federal Employee Health Benefits Program do not cover and pay for off-label uses of prescription drugs, except for in very limited circumstances not applicable here. The off-label uses that were the object of Defendants fraudulent marketing scheme were not 'reasonable and necessary.'

244. As a direct result of Defendant's illegal, false, deceptive and misleading off-label marketing and kickbacks of H.P. Achtar Gel, physicians prescribed Achtar for off-label uses and/or for uses which were not reasonably necessary for treatment. Claims for reimbursement for off-label uses, which were not reasonably necessary, and in fact, medically unnecessary uses of Achtar were submitted to the federal government and the States in connection with such prescriptions, giving rise to liability under their respective False Claims Acts. The United States and the States would not have paid these claims for H.P. Achtar Gel but for Defendant's illegal and fraudulent conduct. Such claims were and in violation of 42 U.S.C. § 1395y(a)(1)(A).

245. The FCA expressly imposes liability on individuals who knowingly cause someone else to submit a false claim for payment. 31 U.S.C. § 3729(a)(1). In interpreting the statute, courts have imposed FCA liability on defendants who caused others to submit false claims for payment, even if the party submitting the claim was unaware of its falsity. *See, e.g., United States v. Bornstein*, 423 U.S. 303 (1976).

246. A claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation, such as the AKS, which is material to the government's decision whether to make payment for the goods or services. Within the theory of false certification, there are two further categories: express and implied false certification.

247. A defendant violates the FCA under express false certification when, in conjunction with a request for Federal funds, it certifies that it is in compliance with regulations that are requirements for payment.

248. An FCA violation occurs under implied false certification when a Defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the noncompliance with a statutory, regulatory, or a contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading. *United States ex rel. Escobar* 579 U.S._, 2016 WL 3317565, slip op., No. 15-7 (June 16, 2016),

249. Liability under the FCA occurs under the implied certification for those who submit claims that make fraudulent misrepresentations, which include misleading omissions if they render the representations misleading with respect to the goods or services. Specifically, representations, like the ones present here, that fall within the rule that "half-truths" - representations that state the truth only so far as it goes, while omitting critical qualifying information - can be actionable. *Id.*

250. Defendants are and were aware that it's fraudulent conduct would cause its pharmacies to submit false claims for reimbursement. *See, e.g., United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d. Cir. 2004) (knowingly assisting in causing the government to pay claims grounded in fraud actionable under FCA); *See also Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S.662 (2008) (noting that a defendant is responsible for the "natural, ordinary and reasonable consequences of his conduct").

251 Defendants introduced H.P. Achtar Gel, using deceptive, misleading and false means to market for off-label uses through the use of illegal kickbacks which were medically unnecessary because the safety and efficacy was unsubstantiated for such off label uses.

252. Contrary to FDA regulations[19], Defendant failed to submit specimens of all off label promotional items and advertisements used and described herein at the time of initial publication on a completed transmittal Form FDA–2253. Submission of this document constitutes a specific and material representation that all promotional items are being disclosed and provided to the FDA. Defendants failure to disclose its non compliance constitutes "half-truth" misrepresentations to FDA.

253. In addition to the above, Defendant was and is required, in view of H.P. Acthar Gel's unusual safety profile submit RAMS Assessments[20] to the FDA at periodic intervals. Defendants failed to disclose the manner and methods, including unscientific comparable studies to FDA along with the required reporting. Submission of these reports constitutes a specific and material representation that all relevant and required information is being disclosed and provided to the FDA.

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[19] *See 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81.* Drug labels - including all marketing and promotional materials relating to the drug - may not describe intended uses for the drug that have not been approved by the FDA. *21 U.S.C. §§ 331, 352.* Illegal "misbranding" can result in criminal penalties. *21 U.S.C. § 333.* Defendant must submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission is required to be accompanied by a completed transmittal Form FDA–2253. This constitutes a specific and material representation that all promotional items are being disclosed and provided to the FDA. Moreover, it constitutes an implied representation that the promotion and marketing that is being done through verbal communications, including inter alia, any drug company's speech or *"advertisement"* for the product subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, is consistent and in line with any written communications being submitted to FDA.

[20] See ¶101 . . . *In view of H.P. Acthar Gel's unusual safety profile, the FDA took the additional, non-standard step when it approved H.P. Acthar Gel for the treatment of IS of also approving a Risk Evaluation and Mitigation Strategy (RAMS) that requires Questcor to distribute an approved Medication Guide with each prescription, and also to submit RAMS Assessments to the FDA at periodic intervals following approval of the RAMS. The approved Medication Guide elaborates on the serious and significant side effects associated with H.P, Acthar Gel.*